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PATENT
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IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants: Fumiki MORIMATSU et al. Conf.: 2745
Serial No.: 08/952,475 Art Unit: 1761
Filed: March 9, 1998 Examiner: CORBIN
For: MEAT PRODUCT HAVING EFFECT OF
INHIBITING INCREASE IN BLOOD
CHOLESTEROL

BRIEF ON APPEAL

RECEIVED

JAN 15 2002

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Assistant Commissioner for Patents
Washington, DC 20231

January 11, 2002

Sir:

This is an appeal from the Office Action (final rejection) that was mailed on May 16, 2001.

1.) Real party in interest.

The real party of interest in this appeal is the Assignee, Nippon Meat Packers, Inc.

2.) Related appeals and interferences.

There are no related appeals or interferences.

3.) Status of claims.

Claims 3, 4, 7, 10, 11, 12, 13, 16, and 17 – which are all of the claims in the case – are rejected. A clean copy of the claims appears in the Appendix.

4.) Status of amendments.

No amendment has been filed subsequent to the final rejection.

5.) Summary of invention.

The meat products of this invention decrease total plasma-cholesterol and plasma-triglyceride levels and increase plasma-HDL-cholesterol levels in humans.

This can be seen, for instance, from the experiment described in lines 1 through 24 on page 12 of the specification. In that experiment, volunteers consumed a diet 110% and 120-130% higher in energy (i.e., calories) and fat than was necessary for adequate daily intake. Even under these conditions, total plasma-cholesterol and plasma-triglyceride levels actually decreased and plasma HDL cholesterol level increased. See also Figures 1-3. This demonstrates that the meat products of the present invention effectively improve plasma-cholesterol levels, even upon consumption of excessive energy (calories) and animal fat.

6.) Issues.

One issue herein is whether claims 3, 4, 7, 10-13, 16, and 17 are properly rejected under 35 USC 103(a) as being unpatentable over *Food Technology*, April 1992, pages 100-108 (Giese).

The other issue herein is whether claims 3, 4, 7, 10-13, 16, and 17 are properly rejected under 35 USC 103(a) as being unpatentable over US 5,164,213 (Bonkowski) in view of US 3,309,204 (Helmer).

7.) Grouping of claims.

The claims herein stand or fall together.

8.) Argument.

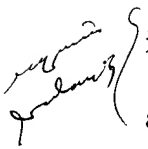
Cholesterol in meat products is mainly derived from animal fat. Table 6 contains three test variables -- # 1 has both animal fat and vegetable oil; # 2 has vegetable oil but no animal fat; # 3 has animal fat but no vegetable oil. The cholesterol content of the test variable **compositions themselves** are in the order: test variable 3 (animal fat only) > test variable 1 (animal fat + vegetable oil) > test variable 2 (vegetable oil only). In contrast, as shown in Table 7, **plasma-cholesterol levels** of rats fed test variables 1-3 fall in the order of test variable 3 (animal fat only) > test variable 2 (vegetable oil only) > test variable 1 (animal fat + vegetable oil). Although, as the Examiner noted in an Advisory Action, the

present invention is intended for use by humans, results obtained in a conventional animal model such as the rat are relevant. In any case, clinical studies on humans are reported on pages 11-12 of the specification.

In other words, even though composition 1 has itself a **higher** cholesterol level than does composition 2, the plasma-cholesterol levels of rats fed Test variable 1 are **lower** than those of rats fed test variables 2. This result is neither taught nor suggested by the references.

The rejection of claims 3, 4, 7, 10-13, 16, and 17 as being unpatentable over Giese is respectfully traversed.

Increasing the amount of vegetable oil in place of animal fat clearly reduces cholesterol content in diets. However, animal fat is often indispensable for favorable texture and flavor in meat products. See, for example, Giese, at page 100, right column, lines 5-7. Increasing the vegetable oil content in meat results

 in loss of favorable texture and flavor such that the meat products are no longer acceptable to the consumer.

To overcome these problems, the present invention adjusts the ratio of vegetable oil and animal fat in meat products to approximately 1:1 ("A meat product containing as lipids approximately the same content of vegetable oil and animal fat").

The presently claimed vegetable oil/animal fat ratio is neither taught nor suggested by such Giese disclosure as that in the last paragraph on page 103:

“Corn, cottonseed, palm, peanut, and soybean oils were partially substituted for beef fat ⁱⁿ low-fat ground beef patties to improve nutritional content.” The rejection over Giese should not be sustained.

The rejection of claims 3, 4, 7, 10-13, 16, and 17 as being unpatentable over Bonkowski in view of Helmer is respectfully traversed.

Bonkowski shows utilization of soy protein in meat products and reduction of their cholesterol contents, but does not disclose any cholesterol-level suppression property *in vivo*. Similarly, Helmer shows utilization of vegetable oil in comminuted meat products to prevent fat cap and emulsion breakdown, but the reference does not disclose any cholesterol-level suppression property *in vivo*. Moreover, the ratios of vegetable oil to animal fat shown by Helmer are quite different from those contemplated by the present invention.

Accordingly, the rejection over Bonkowski in view of Helmer should not be sustained.

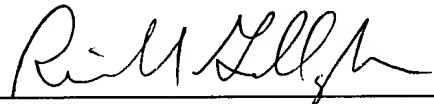
In summary, it is reiterated that the present invention effectively improves the plasma-cholesterol levels upon consumption, even of excessive energy and animal fat, a benefit that is neither taught nor suggested by the references of

record. This improvement is achieved by means of meat products containing vegetable oil and animal fat in a ratio of approximately 1:1 (as well as soy protein isolate – see the paragraph bridging pages 4-5 of the specification).

The rejections over (A) Giese and (B) Bonkowski in view of Helmer should not be sustained.

Respectfully submitted,

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9.) Appendix – clean copy of claims on appeal.

11. A meat product containing as lipids approximately the same content of vegetable oil and animal fat, said meat product comprising:

(a) a fat content of less than half of that present in conventional meat products, and

(b) 8 to 10g of soy protein isolate per 100g of meat product, wherein the meat product possesses a plasma-cholesterol-suppressing property.

3. The meat product claimed in claim 11, wherein the vegetable oil is at least one oil selected from the group consisting of soybean oil, rapeseed oil, safflower oil, sesame oil, and rice-bran oil.

4. The meat product claimed in claim 11, wherein the lipids have a fatty-acid composition (%) comprising myristic acid, 0.5-1.5; myristoleic acid, 0 - 0.2; pentadecanoic acid, 0; palmitic acid, 13.0 - 22.0; palmitoleic acid, 1.5 - 2.5; heptadecanoic acid, 0 - 0.3; heptadecenoic acid, 0 - 0.3; stearic acid, 5.0 - 9.0; oleic acid, 24.0 - 60.0; linoleic acid, 9.0 - 45.0; linolenic acid, 0.2 - 6.0, arachidic acid, 0.1 - 1.0; icosenoic acid, 0.2 - 1.0; and arachidonic acid, 0 - 0.2.

7. The meat product claimed in any one of claims 3, 4, and 11, wherein the meat product is selected from the group consisting of pork sausage, Wiener sausage, Frankfurt sausage, Bologna sausage, loaves, hams, bacon, corned beef, hamburger steak, meat balls, Gyoza and Shumai meats, fresh sausages, bratwursts, ground meat, and seasoned meat.

12. A method for suppressing plasma-cholesterol levels in man, comprising administering a meat product as claimed in claim 11 to man.

13. A method for suppressing plasma-cholesterol levels in man, comprising administering a meat product as claimed in claim 3 to man.

10. The method claimed in one of claims 12 or 13, wherein the meat products are selected from the group consisting of pork sausage, Wiener sausage, Frankfurt sausage, Bologna sausage, loaves, hams, bacon, corned beef, hamburger steak, meat balls, Gyoza and Shumai meats, fresh sausages, bratwursts, ground meat, and seasoned meat.

16. The meat product claimed in claim 11, wherein the meat product is sausage, and the fat content is less than 12.4 g per 100 g of sausage.

17. The meat product claimed in claim 11, wherein the meat product is hamburger steak, and the fat content is less than 7.6 g based on 100 g of hamburger steak.